Nos. 20-70787 & -70801

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, ET AL.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

RURAL COALITION, ET AL.,
Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,
Respondent.

On Petition for Review of an Order of the U.S. Environmental Protection Agency

CROPLIFE AMERICA'S MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE IN SUPPORT OF RESPONDENT U.S. ENVIRONMENTAL PROTECTION AGENCY AND INTERVENORS MONSANTO COMPANY, NATIONAL ASSOCIATION OF WHEAT GROWERS, ET AL.

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Amicus Curiae CropLife America certifies that it has no parent, subsidiaries, or affiliate entities (corporate or otherwise) that have issued stock or debt securities to the public, and no publicly held entity (corporate or otherwise) owns 10% or more of its stock.

MOTION FOR LEAVE TO FILE BRIEF AMICUS CURIAE

Pursuant to Federal Rule of Appellate Procedure 29(a) and this Court's Rule 29-3, Movant CropLife America submits this motion for leave to file the attached amicus brief in support of Respondent U.S. Environmental Protection Agency ("EPA") and the Intervenors in these consolidated proceedings. CropLife's proposed amicus brief addresses critical issues arising under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, including FIFRA's interaction with the Endangered Species Act.[1]

CropLife America, established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CropLife America's member companies

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[1] No party's counsel authored the proposed amicus brief in whole or in part. Bayer Corp., Intervenor Monsanto's parent company, is a member company of CropLife America and pays dues as a member, but, apart from those dues, did not contribute money intended to fund preparation or submission of this brief. No person other than CropLife America and its members contributed money intended to fund preparation or submission of this brief.

This Court's rules provide that "[a] motion for leave to file an amicus brief shall state that movant endeavored to obtain the consent of all parties to the filing of the brief before moving the Court for permission to file." 9th Cir. R. 29-3. Movant CropLife endeavored to obtain consent from all parties, and obtained consent from the NRDC and Pesticide Action Network North America and from all Intervenors. However, EPA and the Rural Coalition petitioners took no position on the request, necessitating this motion.

produce, sell, and distribute virtually all crop protection products, including herbicides, insecticides, and fungicides, which American farmers use to provide consumers with abundant food and fiber. CropLife America is committed to the safe and responsible use of the industry's products.

CropLife America's members are deeply invested in the discovery and development of new crop protection products and product uses and are thus intimately familiar with the comprehensive federal regulation of pesticides under FIFRA and the implementation of the Endangered Species Act, 16 U.S.C. § 1531 *et seq.* as it relates to FIFRA. When EPA makes a registration decision, it does so on the basis of substantial scientific and technical information provided at significant cost to the manufacturers. CropLife America member companies spend, on average, $286 million and 11.3 years on research, development, and registration—roughly the time it took from the creation of NASA to its putting a man on the moon—on crop protection products that reach the marketplace.[2] The costs of registering a new pesticide have increased in recent years, due in large part to a rise in the volume and

[2] *See* Phillips McDougal, "The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014," A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association, 3-4 (March 2016), https://croplife.org/wp-content/uploads/2016/04/Cost-of-CP-report-FINAL.pdf; *see also* Press Release Accompanying Study (Apr. 13, 2016), http://www.croplifeamerica.org/news/2017/10/26/cost-of-crop-protection-innovation-increases-to-286-million-per-product-1 ("Study Press Release").

complexity of environmental safety and toxicology data required by EPA and other regulators.[3] These costs reflect the thoroughness of FIFRA's environmental and human safety review process.

CropLife America's member companies have a keen interest in the legal framework of FIFRA, including FIFRA's distinct registration, registration review, and registration cancellation regulations and procedures, as well as the implementation of the Endangered Species Act as applied to federal pesticide registrations and registration reviews. CropLife America's member companies manufacture and distribute products containing glyphosate, which is the most widely used herbicide in the world—and also one of the most widely studied.

The administrative law issues in the case reach well beyond glyphosate, however. Petitioners erroneously suggest that the expert scientific judgment of EPA exercised in its registration review process can be overridden by stray statements from other organizations or individuals. CropLife America respectfully submits this brief in support of EPA and Intervenors to help the Court understand the regulatory framework of FIFRA, including EPA's role in registering products and reviewing those registrations and the interrelationship between FIFRA and the Endangered Species Act.

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[3] *See* Study Press Release, *supra* n.2.

CONCLUSION

This Court should grant CropLife's motion for leave to file the attached amicus brief.

May 25, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

/s/ Shannen W. Coffin
Shannen W. Coffin

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INTEREST OF THE AMICUS CURIAE[1]

CropLife America, established in 1933, is the national trade association for the plant science industry, representing developers, manufacturers, formulators, and distributors of crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CropLife America's member companies produce, sell, and distribute virtually all crop protection products, including herbicides, insecticides, and fungicides, which American farmers use to provide consumers with abundant food and fiber. CropLife America is committed to the safe and responsible use of the industry's products.

CropLife America's members are deeply invested in the discovery and development of new crop protection products and product uses and are thus intimately familiar with the comprehensive federal regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 *et seq.*, and the implementation of the Endangered Species Act, 16 U.S.C. § 1531 *et seq.* as it relates to FIFRA. When the U.S. Environmental Protection Agency

[1] EPA and the Rural Coalition Petitioners took no position on CropLife's request for consent to file this brief. The NRDC, Pesticide Action Network North America, and all Intervenors consented. CropLife America states that no party's counsel authored this brief in whole or in part. Bayer Corp., Intervenor Monsanto's parent company, is a member company of CropLife America and pays dues as a member, but, apart from those dues, did not contribute money intended to fund preparation or submission of this brief. No person other than CropLife America and its members contributed money intended to fund preparation or submission of this brief.

("EPA") makes a registration decision, it does so on the basis of substantial scientific and technical information provided at significant cost to the manufacturers. CropLife America member companies spend, on average, $286 million and 11.3 years on research, development, and registration—roughly the time it took from the creation of NASA to its putting a man on the moon—on crop protection products that reach the marketplace.[2] The costs of registering a new pesticide have increased in recent years, due in large part to a rise in the volume and complexity of environmental safety and toxicology data required by EPA and other regulators.[3] These costs reflect the thoroughness of FIFRA's environmental and human safety review process.

CropLife America's member companies have a keen interest in the legal framework of FIFRA, including FIFRA's distinct registration, registration review, and registration cancellation regulations and procedures, as well as the implementation of the Endangered Species Act as applied to federal pesticide

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[2] *See* Phillips McDougal, "The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010-2014," A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association, 3-4 (March 2016), https://croplife.org/wp-content/uploads/2016/04/Cost-of-CP-report-FINAL.pdf; *see also* Press Release Accompanying Study (Apr. 13, 2016), http://www.croplifeamerica.org/news/2017/10/26/cost-of-crop-protection-innovation-increases-to-286-million-per-product-1 ("Study Press Release").

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registrations and registration reviews. CropLife America's member companies manufacture and distribute products containing glyphosate, which is the most widely used herbicide in the world—and also one of the most widely studied.

The administrative law issues in the case reach well beyond glyphosate, however. Petitioners erroneously suggest that the expert scientific judgment of EPA exercised in its registration review process can be overridden by stray statements from other organizations or individuals. CropLife America respectfully submits this brief in support of EPA and Intervenors to help the Court understand the regulatory framework of FIFRA, including EPA's role in registering products and reviewing those registrations and the interrelationship between FIFRA and the Endangered Species Act.

INTRODUCTION AND SUMMARY OF ARGUMENT

In enacting and amending FIFRA, Congress delegated to EPA the task of weighing the "economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).[4] EPA has approved the use of glyphosate because it is a highly effective herbicide with a broad spectrum of "use in agriculture, including horticulture, viticulture, and silviculture, as well as non-agricultural sites including commercial, industrial and residential areas."[5] Glyphosate is the leading active ingredient used to control noxious and invasive weeds in aquatic systems, pastures and range lands, forestry, and rights-of-way—thus helping to contain mosquito-borne diseases, keeping roadways and railroad tracks safe, and allowing for distribution of goods, services and utilities.[6] At the same time, EPA has not "identif[ied] any human health risks from exposure to any use of glyphosate."[7]

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[4] Cornell University's Pesticide Safety Education Program has prepared a useful guide to the factors considered by EPA in its FIFRA risk/benefit analysis, http://psep.cce.cornell.edu/issues/risk-benefit-fifra.aspx.

[5] *See* U.S. EPA, Glyphosate: Proposed Interim Registration Review Decision, Case No. 0178, at 34 (Apr. 2019), https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0361-2344.

[6] *Id.*

[7] *Id.* at 35; U.S. EPA, Glyphosate: Interim Registration Review Decision, Case No. 0178, at 15 (Jan. 2020), https://www.epa.gov/sites/production/files/2020-01/documents/glyphosate-interim-reg-review-decision-case-num-0178.pdf.

Reflecting this combination of low risk and high reward, "[g]lyphosate is the most commonly used agricultural herbicide in the United States, in terms of area treated."[8]

Petitioners challenge EPA's 2020 "Interim Registration Review Decision" for glyphosate, in which EPA reaffirmed its longstanding position, based on decades of expert analysis, that "there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans."[9] CropLife America submits this amicus brief to address several additional points.

First, Petitioners' argument that EPA is required to engage in Endangered Species Act consultation with other federal agencies prior to issuing an interim registration review decision misunderstands EPA's relevant procedures, which Congress granted EPA broad discretion to establish. Because of the length of time needed to fully conduct pesticide registration review, EPA's regulations permit it to issue an "interim registration review" decision "when it does not have the data necessary to complete a registration review but it does have sufficient information to determine that new risk mitigation measures are needed." *See* 70 Fed. Reg. 40,251, 40,268 (July 13, 2005). The entire point of this interim registration review process is to permit the agency flexibility to address aspects of the data and propose mitigation where it has not yet fully conducted all of the review necessary to

[8] Proposed Interim Registration Review Decision at 34.

[9] Interim Registration Review Decision at 10.

complete registration review. That EPA has not yet completed Endangered Species Act procedures does not invalidate the agency's action here, as EPA will have the opportunity to undertake any necessary consultation course before completing its registration review. EPA is proceeding this way because of the complicated nature of those consultations, which have long raised systemic issues of inter-agency cooperation. EPA is fully committed to engaging in the necessary consultations, *see* EPA Br. 65 & n.18, and this Court should allow that process to play out without judicial intervention.

Second, EPA's health assessment is both valid and lawful. With respect to EPA's health effects determination, EPA carefully considered the prevailing data, including the flawed finding by the International Agency for Research on Cancer ("IARC") that glyphosate may cause cancer, which EPA rationally rejected as unsubstantiated. EPA's health assessment is reasonable and fully consistent with FIFRA and the Administrative Procedure Act.

Finally, Petitioners would not be entitled to the remedy they seek even if their challenges to that assessment were well founded. Petitioners contend that the Court should somehow vacate the underlying existing glyphosate registrations and thereby institute a judicial ban on the use of this crucial agricultural input. But this sweeping remedy is unavailable in judicial review of an interim *registration review* decision. FIFRA provides a separate procedure for cancelling existing registrations, and

makes clear that no registration can be cancelled as a result of a registration review unless that process has been followed (which is not the case here). Both statutory text and fundamental principles of administrative law confirm that, at most, a court reviewing a *final* registration review decision (which this is not) might vacate *the registration review* decision—which would not affect the underlying EPA glyphosate registrations. Petitioners have offered no basis to conclude otherwise, especially where, as here, the agency decision at issue is merely an interim decision.

BACKGROUND

I. FIFRA'S COMPREHENSIVE REGULATION OF PESTICIDE REGISTRATIONS

FIFRA is a "comprehensive regulatory statute." *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984). It governs the sale, use and labeling of "pesticides," a term that includes not only substances intended to prevent and control pests, but also "any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." 7 U.S.C. § 136(u).

Three separate regulatory processes established by FIFRA are relevant here: the registration process, the registration review process (which includes the interim registration review process at issue), and the registration cancellation process. We describe them briefly here.

A. The FIFRA Registration Process

Pesticide registration is the process by which EPA initially considers whether to allow the use of a pesticide and establishes conditions for lawful use. *See* 7 U.S.C. §§ 136a(a), (c). FIFRA makes it unlawful for any person to "distribute or sell to any person any pesticide that is not registered" under the statute. 7 U.S.C. § 136a(a). The FIFRA registration process requires EPA to comprehensively evaluate product safety and risks to human health and the environment in registering any pesticide.[10] The statute and its implementing regulations thus require registrants to provide substantial scientific data to support the safety and health effects of a pesticide. *See* 7 U.S.C. §§ 136a(c)(1)(F), (c)(2)(A); *see also* 40 C.F.R. pt. 158. A registrant must submit substantial data relating to the toxicology of the pesticide, including studies relating to the likelihood that the pesticide could cause cancer in laboratory rodents. 40 C.F.R. § 158.500(d).

EPA "shall register a pesticide" only if it determines that, "when considered with any restrictions imposed," the pesticide meets four general requirements: (1) its composition is such as to warrant the proposed claims for it; (2) its labeling and the other material required to be submitted comply with the requirements of FIFRA; (3) it will perform its intended function without unreasonable adverse effects on the

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[10] *See* EPA Pesticide Registration Manual: Introduction, https://www.epa.gov/pesticide-registration/pesticide-registration-manual-introduction.

environment; and (4) when used in accordance with widespread and commonly recognized practice, it will not generally cause unreasonable adverse effects on the environment. *See* 7 U.S.C. § 136a(c)(5).

The statute defines "unreasonable adverse effects on the environment" to mean "any unreasonable risk to man or the environment," a calculus that requires EPA to balance the "economic, social, and environmental costs and benefits of the use of any pesticide." *Id.* § 136(bb). It also includes "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under" the Food, Drug & Cosmetic Act. *Id.*

A central focus of EPA's registration process is review and approval of the product's label. A "critical function of the label is to translate the results of the science evaluations into a set of conditions, directions, precautions, and restrictions that define who may use a pesticide, as well as where, how, how much, and how often it may be used."[11] EPA will not register a pesticide unless it "has determined that the product is not misbranded . . . and its labeling and packaging comply with the applicable requirements" of FIFRA and its regulations. 40 C.F.R. § 152.112(f).

[11] U.S. EPA, Office of Pesticide Programs, Label Review Manual, at 1-2, https://www.epa.gov/sites/production/files/2021-02/documents/full-lrm_2-22-21.pdf.

It is unlawful to distribute or sell any misbranded pesticide. 7 U.S.C. § 136j(a)(1)(E).

B. The Registration Review Process

Once EPA has registered a pesticide pursuant to the process described above, FIFRA requires EPA to "review" that registration every 15 years. *See* 7 U.S.C. §§ 136a(g)(1)(A)(i), (iii)-(iv). "Registration review is the periodic review of a pesticide's registration to ensure that each pesticide registration continues to satisfy the FIFRA standard for registration." 40 C.F.R. § 155.40(a). FIFRA says little about what a registration review must entail, instead authorizing the agency to "by regulation establish a procedure for accomplishing the periodic review of registrations." 7 U.S.C. § 136a(g)(1)(A)(ii).

EPA has promulgated regulations establishing a procedure for registration review. *See* 40 C.F.R. § 155.40 *et seq.* Those regulations explain that "[r]egistration review is intended to ensure that each pesticide's registration is based on current scientific and other knowledge regarding the pesticide, including its effects on human health and the environment." *Id.* § 155.40(a)(1). During the registration review, EPA "will assess any changes that may have occurred since [EPA's] last registration decision in order to determine the significance of such changes and whether the pesticide still satisfies the FIFRA standard for registration." *Id.*

§ 155.53(a). This procedure involves a review of "any new data or information on the pesticide." *Id.*; *see also id.* § 155.50.

The final outcome of the registration review process is a "[r]egistration review decision." *Id.* § 155.57. "A registration review decision is [EPA's] determination whether a pesticide meets, or does not meet, the standard for registration in FIFRA." *Id.* A decision may, among other things, "[s]tate [EPA's] proposed findings with respect to the FIFRA standard for registration," "[i]dentify proposed risk mitigation measures or other remedies as needed," and/or "[s]pecify proposed labeling changes." *Id.* § 155.58(b).

Because some aspects of the registration review process take longer than others, EPA's regulations provide that it "may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review." *Id.* § 155.56. An "interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review." *Id.*

EPA's regulations provide for "[p]ublic participation during a pesticide's registration review." *Id.* § 155.53(c). EPA "will generally make available for public review and comment a draft risk assessment" if it conducts a new assessment as part

of the review process. *Id.* Following "a comment period of at least 30 calendar days," EPA "will publish a notice in the Federal Register announcing the availability of a revised risk assessment, an explanation of any changes to the proposed document, and its response to comments." *Id.* EPA will also "publish a notice in the Federal Register announcing the availability of a proposed registration review decision or a proposed interim registration review decision. . . . There will be a comment period of at least 60 calendar days on the proposed decision." *Id.* § 155.58(a).

"After considering any comments on the proposed decision, [EPA] will issue a registration review decision or interim registration review decision," which "will include an explanation of any changes to the proposed decision and [EPA's] response to significant comments." *Id.* § 155.58(c). "If the registrant fails to take the action required in a registration review decision or interim registration review decision, [EPA] may take appropriate action under FIFRA." *Id.* § 155.58(d).

C. The Registration Cancellation Process

Congress explicitly limited EPA's authority to cancel a registration directly as part of a registration review: "No registration shall be canceled as a result of the registration review process unless the [EPA] follows the procedures and substantive requirements of section 136d." *Id.* § 136a(g)(1)(A)(v). Section 136d empowers EPA to cancel a pesticide registration after a registration review only after providing

additional process to the registrant and making findings about the impact of such a cancellation. EPA's regulations contemplate that EPA may institute cancellation proceedings where a registration review reveals that an existing registration no longer satisfies the statutory requirements for registration: "If a product fails to satisfy the FIFRA standard for registration, the product's registration may be subject to cancellation or other remedies under FIFRA." 40 C.F.R. § 155.40(a)(2).

Though Petitioners never mention it, § 136d provides the exclusive route to cancel an existing registration like a glyphosate registration. It states that, "[i]f it appears to the [EPA] that a pesticide . . . generally causes unreasonable adverse effects on the environment, the [EPA] may issue a notice of the [EPA's] intent either—(1) to cancel its registration . . . , or (2) to hold a hearing to determine whether or not its registration should be canceled." *Id.* § 136d(b). EPA must consider "the impact of the action proposed in such notice on production and prices of agricultural commodities, retail food prices, and otherwise to the agricultural economy." *Id.* EPA must "provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy." *Id.* Any "person adversely affected by the notice" is entitled to request an administrative hearing. *Id.* Finally, before cancelling a registration, EPA must both "consider restricting a pesticide's use or uses as an alternative to cancellation" and publish in the Federal

Register its analysis of "the impact of [cancellation] on production and prices of agricultural commodities" and "retail food prices." *Id.*

II. EPA'S INTERIM REGISTRATION REVIEW DECISION FOR GLYPHOSATE

In January 2020, after extensive scientific analysis of the health and environmental effects of glyphosate, EPA issued its interim registration review decision for glyphosate.[12] In the nine months between the issuance of the proposed interim decision and the issuance of the finalized interim decision, EPA received "[o]ver 12,000 unique submissions . . . from various stakeholders, including glyphosate registrants, grower groups, non-governmental organizations, pesticide industry groups, states, the U.S. Department of Agriculture and members of the general public" during the course of a 120-day comment period.[13]

EPA explained that the purpose of the interim decision was to "(1) move forward with aspects of the registration review case that are complete and (2) implement interim risk mitigation."[14] EPA acknowledged that it "ha[d] not yet fully evaluated risks to federally-listed species" pursuant to § 7 of the Endangered Species Act, and stated that it would "complete its listed species assessment and any

[12] *See* Interim Registration Review Decision, *supra* n.7.

[13] *Id.* at 5.

[14] *Id.* at 3.

necessary consultation with [other federal agencies] prior to completing the glyphosate registration review."[15]

At the same time, EPA's interim registration review fully reaffirmed EPA's conclusion that glyphosate does not cause cancer in humans. The interim decision states: "None of the open literature studies identified for the agency's consideration were found to have an impact on the glyphosate hazard characterization, cancer assessment, or human health risk assessment. The agency will continue to monitor the open literature for studies that use scientifically sound and appropriate methodology and relevant routes of exposure that have the potential to impact the risk evaluation of glyphosate."[16] EPA reaffirmed that it had "thoroughly evaluated potential human health risk associated with exposure to glyphosate and determined that there are no risks to human health from the current registered uses of glyphosate and that glyphosate is not likely to be carcinogenic to humans. . . . EPA found there was insufficient evidence to conclude that glyphosate plays a role in any human diseases."[17]

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[15] *Id.*; *see also id.* at 15 ("the agency is not making a complete endangered species finding at this time"); *id.* at 20 ("The agency's final registration review decision for glyphosate will be dependent upon the result of the agency's [Endangered Species Act] assessment").

[16] *Id.* at 7.

[17] *Id.* at 10; *see also id.* at 9 (EPA "thoroughly assessed risks to humans from exposure to glyphosate from all registered uses and all routes of exposure and did not identify any risks of concern"); *id.* at 15.

The interim decision requires certain mitigation measures addressing the way that glyphosate is used that are intended to protect non-human organisms from "spray drift," a phenomenon in which pesticides sprayed onto a field drift to adjacent areas.[18] The additional mitigation measures, which must be added to the labels on glyphosate products, include prohibitions on spraying during temperature inversions and limits on the length of booms used to apply pesticides from aircraft.[19] These additional measures will "reduce off-target spray drift and establish a baseline level of protection against spray drift that is consistent across all glyphosate products," thereby "reduc[ing] the extent of environmental exposure and risk to non-target plants and animals."[20]

ARGUMENT

I. EPA IS NOT REQUIRED TO COMPLETE ENDANGERED SPECIES ACT CONSULTATIONS PRIOR TO ISSUING AN INTERIM REGISTRATION REVIEW DECISION

Petitioners are incorrect in arguing that EPA's failure to consult with other expert federal agencies regarding the impact of glyphosate registration review prior to issuing its interim decision invalidates the entire proceeding. Petitioners' argument fails to take account of the interim nature of the decision under review.

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[18] *See id.* at 15-17.

[19] *Id.* at 15-16.

[20] *Id.* at 15.

The Endangered Species Act consultation is one of the more complex aspects of the registration review process. Perhaps owing to that complexity, and the length of time required to undertake those consultations, EPA's regulations do not require EPA to complete those consultations prior to taking the sort of interim action at issue here. 40 C.F.R. § 155.56 provides that EPA may, when the circumstances warrant, take action short of a final review decision. The agency "may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review." *Id.* This "interim registration review decision may require new risk mitigation measures, impose interim risk mitigation measures, identify data or information required to complete the review, and include schedules for submitting the required data, conducting the new risk assessment and completing the registration review." *Id.*

The very nature of these regulations demonstrates that the agency may act *before* it has all the data necessary to complete its final registration review. And thus it properly has determined that imposing mitigation measures need not wait for the Endangered Species Act consultations to be completed. This delay is prompted by the complexity of the consultation process, which has long confounded relevant stakeholders. As one former EPA senior official and a Fish and Wildlife Service official described, the consultation process involves "multiple agencies, mandates, and differing staff expertise, reconciling multiple statutory provisions, in the face of

declining resources, a litigation-rich environment, and complex and sometimes uncertain science." *See* Avi Garbow & Paul Souza, *Aligning Imperiled Species Conservation and Pesticide Registrations*, 33 Va. Envt'l L.J. 172, 174-76 (2015). It is thus no surprise that EPA has opted to take interim action before completing that cumbersome and complicated review.

EPA's course of action here is best viewed in the context of the longstanding tension between FIFRA and the Endangered Species Act. When Congress amended the Endangered Species Act in 1988, it directed that Endangered Species Act compliance for pesticide registrations be designed "to minimize the impacts to persons engaged in agricultural food and fiber commodity production and other affected pesticide users and applicators." Endangered Species Act Amendments of 1988, Pub. L. 100-478 § 1010, 102 Stat. 2306, 2313 (Oct. 7, 1988); 7 U.S.C. § 136a note. The Conference Report to that bill concluded that Congress anticipated that EPA, the Fish and Wildlife Service, and other relevant agencies should "implement the Endangered Species Act in a way that protects endangered and threatened species while minimizing, where possible, impacts on production of agriculture foods and fiber commodities." H.R. Conf. Rep. No. 100-928, at 23-24 (1988), *reprinted in* 1988 U.S.C.C.A.N. 2738, 2741-42.

That task has confounded the federal agencies involved in FIFRA-Endangered Species Act review. The "interplay between the [Endangered Species Act] and

FIFRA was challenging from the start." Garbow & Souza, 33 Va. Envt'l L.J. at 174-76. Consultation on particular pesticide registrations can take many years—sometimes even decades—to complete. One prior lawsuit resulted in a court order requiring EPA to make Endangered Species Act effects determinations on 54 pesticides and to initiate Endangered Species Act consultation on a pesticide if EPA made a "may affect" determination. *See Wash. Toxics Coal. v. EPA*, No. C01-132C, 2002 WL 34213031 (W.D. Wash. July 2, 2002). Nearly twenty years later, the U.S. Fish & Wildlife Service and the National Marine Fisheries Service (together, "the Services") still have not completed Endangered Species Act consultation on some of those pesticides.

For many years, EPA and the Services adopted different approaches to analyzing the impact of pesticides on endangered species population. Disputes between the agencies led to nearly a decade of negotiations between EPA and the Services on how best to conduct these consultations.[21] EPA and the Services sought advice from the National Academy of Sciences ("NAS") and in 2013, the NAS published a report providing guidance to EPA and the Services on key scientific issues at the heart of the agencies' disagreements and recommending they develop

[21] CropLife discussed the relevant history in greater length in a recently filed amicus brief in the D.C. Circuit. *See* Brief of Amicus Curiae CropLife America, *Farmworkers Ass'n of Florida v. EPA*, No. 21-1079, Doc. # 1895361 (D.C. Cir. filed Apr. 20, 2021).

common scientific methodologies and approaches.[22] The report also recognized that EPA's risk assessment approach adequately protects endangered species.[23] In 2014, driven by its recognition that "the need for Endangered Species Act compliance does not override" FIFRA's registration review deadlines, Congress urged EPA and the Services to develop processes and procedures to integrate requirements under FIFRA and the Endangered Species Act in a way that "assure[s] EPA can meet its statutory deadlines." *See* H.R. Conf. Rep. No. 113-333, at 531-32 (2014), *reprinted in* 2014 U.S.C.C.A.N. 12, 177-78.

What followed were extended efforts by the relevant federal agencies to find a way forward. The agencies adopted a pilot program in 2015, but that program proved cumbersome and took EPA and the services three years to address a mere three of the 700-plus active ingredients for which EPA must complete FIFRA registration review by October 2022. EPA and the Departments of the Interior and Commerce subsequently established an interagency work group to explore additional ways to improve the Endangered Species Act review process for

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[22] *See* National Research Council of the National Academies, *Assessing Risks to Endangered and Threatened Species from Pesticides* (2013), https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides.

[23] *See, e.g.*, *id.* at 5 ("[T]he committee concludes that the risk-assessment paradigm reflected in the ecological risk assessment (ERA) process is singularly appropriate for evaluating risks posed to ecological receptors, such as listed species, by chemical stressors, such as pesticides. . . .").

pesticides. Congress later codified this interagency work group and required the submission of regularly scheduled reports to Congress. *See* Agricultural Act of 2018, Pub. L. 115-334 § 10115, 132 Stat. 4490 (Dec. 20, 2018).

In the past two years, EPA has worked with other federal agencies to develop a Revised Method for conducting Endangered Species Act analyses for pesticides. After extensive public engagement and interagency reviews, EPA issued an updated Revised Method in March 2020.[24] EPA continues to work with stakeholders to refine the Revised Method.

As even this abbreviated history illustrates, EPA faces significant hurdles in implementing its consultation obligations under the Endangered Species Act. Yet, as CropLife attests, EPA has, to date, acted in good faith to develop a workable solution that both ensures protection of listed species and allows EPA to meet the statutory deadlines under FIFRA for its exhaustive scientific assessments. EPA's efforts to ensure a properly functioning pesticide evaluation program are vital to the crop protection industry's ability to provide important, beneficial products that contribute to agricultural productivity and respond to the development of pest resistance.

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[24] *See* U.S. EPA, Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides (Mar. 12, 2020), https://www3.epa.gov/pesticides/nas/revised/revised-method-march2020.pdf.

In this case, EPA has committed to completing the Endangered Species Act consultation process as a result of a litigation settlement in which CropLife America participated. *See* EPA Br. 65 & n.18. Consistent with that commitment, EPA released a draft biological evaluation for glyphosate in November 2020.[25] EPA's decision to issue the interim decision before it completed the draft biological evaluation is supported by the evolution of the process to harmonize the requirements of the Endangered Species Act and FIFRA. It should be permitted the additional time needed to complete this complex inter-agency process.

II. EPA'S INTERIM GLYPHOSATE REGISTRATION REVIEW DECISION REASONABLY CONCLUDED, BASED ON CURRENTLY AVAILABLE EVIDENCE, THAT GLYPHOSATE DOES NOT POSE A THREAT TO HUMAN HEALTH

Petitioners further challenge EPA's interim registration review decision's conclusion that glyphosate does not pose a threat to human health. CropLife America does not wish to belabor the thorough analysis of EPA on this question (*see* EPA Br. 24), but writes briefly to highlight some of the errors of Petitioners' challenge as it relates to EPA's proper conclusion that glyphosate does not pose a cancer risk.

EPA issued its initial glyphosate registration in 1974 and issued a Reregistration Eligibility Decision for the active ingredient glyphosate, after a

[25] *See* U.S. EPA, Draft National Level Listed Species Biological Evaluation for Glyphosate (Nov. 2020), https://www.epa.gov/endangered-species/draft-national-level-listed-species-biological-evaluation-glyphosate.

thorough examination of the underlying data, in 1993.[26] In the nearly 50 years since the original registration, EPA has repeatedly concluded that glyphosate does not pose a cancer risk. Acting on the recommendation of a scientific peer review committee in the early 1990s, EPA found "evidence of no carcinogenicity for humans."[27] It reiterated that finding in a formal rule in 1997[28] and repeatedly in subsequent rulemakings.[29]

In 2009, EPA initiated this registration review, a process that has been conducted over a decade and has entailed extensive review of glyphosate's environmental safety and toxicology.[30] After further review by both EPA's Cancer Assessment Review Committee and a Scientific Advisory Panel, EPA published a Revised Glyphosate Issue Paper evaluating the carcinogenic potential of the

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[26] *See* U.S. EPA, Ingredients Used in Pesticide Products: Glyphosate, https://www.epa.gov/ingredients-used-pesticide-products/glyphosate; U.S. EPA, Reregistration Eligibility Decision (RED): Glyphosate (Sept. 1993).

[27] *See* U.S. EPA, R.E.D. Facts, Glyphosate, at 2 (Sept. 1993), https://archive.epa.gov/pesticides/reregistration/web/pdf/0178fact.pdf.

[28] Final Rule: Glyphosate; Pesticide Tolerances, 62 Fed. Reg. 17,723, 17,724 (Apr. 11, 1997).

[29] Final Rule: Glyphosate; Pesticide Tolerances, 67 Fed. Reg. 60,934, 60,936 (Sept. 27, 2002); *see also* Final Rule: Glyphosate; Pesticide Tolerances, 73 Fed. Reg. 73,586, 73,589 (Dec. 3, 2008).

[30] *See* Ingredients Used in Pesticide Products: Glyphosate. FIFRA requires EPA to "complete the registration review" for glyphosate by October 1, 2022, and then "each 15 years thereafter." 7 U.S.C. §§ 136a(g)(1)(A)(iii)-(iv).

herbicide in December 2017.[31] "As part of this process, the hazard and exposure of glyphosate are reevaluated to determine its potential risk to human and environmental health," incorporating "new science."[32] The extensive review included assessment of "63 epidemiological studies, 14 animal carcinogenicity studies, and nearly 90 genotoxicity studies for the active ingredient glyphosate."[33] The agency concluded that "available data and weight-of-evidence clearly do not support the descriptors 'carcinogenic to humans,'" or even "'likely to be carcinogenic to humans.'"[34] Instead, EPA concluded that the scientific evidence most strongly supported a description of glyphosate as "not likely to be carcinogenic to humans."[35]

Notably, this assessment was concluded *after* IARC announced its view, upon which Petitioners heavily rely, that glyphosate was a probable carcinogen. EPA's 2019 "Proposed Interim Registration Review Decision" for glyphosate reaffirmed the agency's conclusion that its "independent evaluation of the carcinogenic

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[31] *See* U.S. EPA, Office of Pesticide Programs, Revised Glyphosate Issue Paper: Evaluation of Carcinogenic Potential (Dec. 12, 2017), https://usrtk.org/wp-content/uploads/2019/04/REVISED_GLYPHOSATE_ISSUE_PAPER_EVALUATION_OF_CARCINOGENIC_POTENTIAL-1.pdf.

[32] *Id.* at 12.

[33] *Id.* at 144.

[34] *Id.*

[35] *Id.*

potential of glyphosate . . . has determined that glyphosate is 'not likely to be carcinogenic to humans.'"[36] Despite Petitioners' suggestion that EPA improperly disregarded the IARC analysis, the agency considered and expressly rejected IARC's cancer conclusion, explaining that EPA's "cancer evaluation is more robust than IARC's evaluation," which "only considered a subset of the studies included in the EPA's evaluation" and included "some studies [excluded by EPA] that were not appropriate for determining the human carcinogenic potential of glyphosate."[37]

Petitioners contend that EPA "failed to comply with its own Cancer Guidelines" in determining that glyphosate does not cause cancer. Rural Coalition Br. 38. As EPA has explained in detail, however, this accusation is false and is based on a misunderstanding of the Guidelines.[38] "The 2005 EPA Guidelines for Carcinogen Risk Assessment are intended as a guidance only and does not provide a checklist for determining whether tumor findings are related to treatment."[39] And the Guidelines' statement that "[s]ignificance in either [trend tests and pairwise comparison tests] is sufficient to reject the hypothesis that chance accounts for the

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[36] *See* Proposed Interim Registration Review Decision at 7.

[37] *Id.*

[38] *See* U.S. EPA Memo. Regarding Response to the Final Report of the FIFRA Scientific Advisory Panel on the Evaluation of the Human Carcinogenic Potential of Glyphosate, 6-9 (Dec. 12, 2017), https://www.regulations.gov/document/EPA-HQ-OPP-2009-0361-0072.

[39] *Id.* at 6-7.

result" "is referring generally to the fact that in all statistical analyses a hypothesis is rejected when statistical significance occurs. This does not imply that statistical significance alone in an individual test is sufficient to determine that observed tumors are treatment-related."[40]

Reaffirming its conclusion in an August 2019 letter to all glyphosate registrants, EPA's Office of Pesticide Programs reiterated that it "disagrees with IARC's assessment of glyphosate."[41] EPA noted that its cancer classification is "consistent with other international expert panels and regulatory authorities," including government regulators in Canada, Australia, Germany, and New Zealand, as well as the European Food Safety Authority and European Chemical Agency.[42] Similarly, at least one federal judge in this Circuit has agreed with EPA, barring California from requiring cancer warning labels on glyphosate products based on IARC's erroneous assessment. *See National Ass'n of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020). EPA has thus concluded, based on its

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[40] *Id.* at 7.

[41] U.S. EPA, Letter to Glyphosate Registrants on California Proposition 65, at 1 (Aug. 7, 2019), https://www.epa.gov/sites/production/files/2019-08/documents/glyphosate_registrant_letter_-_8-7-19_-_signed.pdf.

[42] *Id.*

independent evaluation of the scientific evidence, that products containing a cancer warning for glyphosate would be "misbranded pursuant to" FIFRA.[43]

In short, EPA's conclusion that glyphosate does not pose a risk of cancer or any other serious health effects in humans is both rational and well supported by the available evidence. EPA has "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicles Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*, 463 U.S. 29, 42-43 (1983). The Administrative Procedure Act requires affirmance.

III. THIS PROCEEDING PROVIDES NO OPPORTUNITY FOR THE COURT TO CONSIDER WHETHER TO VACATE EXISTING GLYPHOSATE REGISTRATIONS

Even if Petitioners were able to identify some shortcoming in EPA's process to date, the remedy they seek is wildly overreaching and unsupported by the law. Petitioners are candid about their ultimate goal in challenging the interim registration review decision: They ask this Court to "vacate EPA's unlawful glyphosate registration," with the result that "glyphosate use would be unlawful" in the United States. Rural Coalition Br. 80-81; *see id.* at 79-81; NRDC Br. 69-73 (same). As the statutory framework set forth above makes clear, however, vacatur of the underlying

[43] *Id.*

registrations is not a possible remedy when a court reviews an EPA decision in the context of registration *review*.

EPA issued the first glyphosate registration in 1974 and completed a Reregistration Eligibility Decision in 1993. Those decades-old registration decisions are not now before the Court. Rather, Petitioners seek review of EPA's interim *registration review* decision. While FIFRA mandates that EPA conduct such a review of existing registrations every 15 years, nothing in FIFRA suggests that EPA's failure to complete a satisfactory review would invalidate *the underlying registration*. To the contrary, the clause of FIFRA's registration review provision titled "Cancellation" states: "No registration shall be canceled as a result of the registration review process unless [EPA] follows the procedures and substantive requirements of section 136d," which creates a separate process for EPA to follow to cancel an existing registration. 7 U.S.C. § 136a(g)(1)(A)(v).

Section 136d provides necessary due process protections to the registrant and requires EPA to make additional factual findings about the real-world effects of a cancellation decision. Congress's decision to require these additional processes before any registration could be cancelled makes good sense. "A FIFRA registration is a product-specific license." *Reckitt Benckiser Inc. v. EPA*, 613 F.3d 1131, 1133 (D.C. Cir. 2010). And "licenses are property interests that cannot be deprived

without procedural due process." *Industrial Safety Equipment Ass'n v. EPA*, 837 F.2d 1115, 1122 (D.C. Cir. 1988) (citing *Bell v. Burson*, 402 U.S. 535, 539 (1971)).

Accordingly, § 136d requires public "notice of the [EPA's] intent either" to cancel a registration or hold a hearing on whether a registration should be cancelled. 7 U.S.C. § 136d(b). As a safeguard against the sort of extraordinary agricultural and economic disruption that a cancellation could cause, § 136d requires EPA to consider "the impact of the action proposed . . . on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy." *Id.*; *see also, e.g.*, *National Family Farm Coalition v. EPA*, 966 F.3d 893, 929-30 (9th Cir. 2020) (describing "evidence of potentially serious disruption [that would occur] if a pesticide that has been registered for over five years can no longer be used"). Section 136d also generally requires advance notice to the Department of Agriculture. *See* 7 U.S.C. § 136d(b). And it requires that, before cancelling a registration, EPA must also "consider restricting a pesticide's use or uses as an alternative to cancellation" and must publish in the Federal Register its analysis of "the impact of [cancellation] on production and prices of agricultural commodities" and "retail food prices." *Id.*

Allowing a private party to obtain judicial invalidation of an existing registration merely by challenging a registration review decision, as Petitioners suggest here, would nullify the statutory scheme that Congress established through

§ 136d. Not surprisingly, then, Petitioners do not point to any case suggesting that a court may vacate a pesticide registration as a remedy for a flaw in a registration review decision. *Pollinator Stewardship Council v. EPA* was a challenge to EPA's *initial registration* of "insecticides containing sulfoxaflor." 806 F.3d 520, 522 (9th Cir. 2015). This Court held that "EPA's *decision to unconditionally register* sulfoxaflor was based on flawed and limited data" and "therefore vacate[d] the EPA's registration" and remanded for further consideration. *Id.* (emphasis added). The case thus stands only for the commonsense proposition that vacatur of a registration is a possible remedy where the petitioner seeks review of the registration decision itself. Likewise, in *National Family Farm Coalition v. EPA*, this Court considered a challenge to the initial EPA "decision upon which the registrations [of certain dicamba-based herbicides] were based" and "vacate[d] the EPA's October 31, 2018, registration decision and the three registrations premised on that decision." 960 F.3d 1120, 1124-25 (9th Cir. 2020). Here, of course, the glyphosate registrations are not "premised" on EPA's interim registration review decision—which is the only agency action before this Court.

Petitioners' other cited cases stand only for the general proposition that a court that determines that a challenged agency action was contrary to law can choose between vacating *that action* and remanding it to the agency without vacatur. *See Alliance for the Wild Rockies v. U.S. Forest Service*, 907 F.3d 1105, 1121 (9th Cir.

2018); *Idaho Farm Bureau Federation v. Babbitt*, 58 F.3d 1392, 1405 (9th Cir. 1995). Regardless of whether the Court vacates the action now before it (the interim registration review decision), the existing glyphosate registrations will remain in force unless EPA undertakes to cancel them pursuant to § 136d.[44]

The relevant statutes are to the same effect. The Administrative Procedure Act empowers a reviewing court to "hold unlawful and set aside agency action" that is "not in accordance with law." 5 U.S.C. § 706(2). The "agency action" here is the interim registration review decision, and "set[ting] aside" that decision would not affect the underlying registrations. Similarly, FIFRA's judicial review provision says that the filing of a petition for review gives the Court "exclusive jurisdiction to affirm or set aside *the order complained of* in whole or in part." 7 U.S.C. § 136n(b) (emphasis added). Here, the "order complained of" is the interim registration review decision.

Even if (unlike with glyphosate) EPA determined in the course of a registration review that a particular pesticide registration did pose a threat to human health, FIFRA would still require it to "follow[] the procedures and substantive requirements of section 136d" before it could cancel the registration. 7 U.S.C.

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[44] *California ex rel. Lockyer v. USDA*, 575 F.3d 999, 1018 (9th Cir. 2009), which Petitioners cite for the proposition that § 7 of the Endangered Species Act is that statute's "heart" (Rural Coalition Br. 80), similarly says nothing about remedies in the context of FIFRA registration review decisions.

§ 136a(g)(1)(A)(v). Plainly, then, a court cannot cancel a registration simply because it finds that EPA's registration review decision was unsatisfactory. At most, a court in that situation could remand to EPA (with or without vacatur) to correct the flaws in its decision.

In short, Petitioners' attempt to cancel glyphosate registrations by challenging the interim registration review decision subverts the statutory scheme and undermines the congressionally imposed safeguards contained in § 136d. Regardless of how the Court rules on the merits of Petitioners' challenge to the interim decision, it should make clear that § 136d provides the exclusive route for the cancellation of an existing registration.[45]

[45] Relatedly, to the extent this Court finds flaws in the interim registration review decision, the appropriate remedy would be to remand without vacatur. *See California Communities Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012); *National Family Farm Coalition*, 966 F.3d at 929 (remanding without vacatur where, "given the technical nature of the EPA's error, EPA will 'likely be able to offer better reasoning' and 'adopt the same rule on remand'"). Remand without vacatur would simply leave in place the interim decision's mitigation measures, which Petitioners themselves are likely to support. Petitioners' request for vacatur is based instead on their mistaken belief that vacatur of the interim decision would result in a court-ordered ban on all use of glyphosate.

CONCLUSION

The Court should deny the petitions for review.

May 25, 2021

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 32(a)(7)(C), the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B)(i) and Rule 29(a)(5).

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 32(a)(7)(B), the brief contains 6,920 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2019 in 14-point Times New Roman font. As permitted by Fed. R. App. P. 32(a)(7)(B), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

May 25, 2021

/s/ Shannen W. Coffin
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CERTIFICATE OF SERVICE

I hereby certify that on May 25, 2021, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

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